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Lex genetica: The law and ethics of programming biological code

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Abstract. Recent advances in genetic engineering now allow the design of programmable biological artifacts. Such programming may include usage constraints that will alter the balance of ownership and control for biotechnology products. Similar changes have been analyzed in the context of digital content management systems, and while this previous work is useful in analyzing issues related to biological programming, the latter technology presents new conceptual problems that require more comprehensive evaluation of the interplay between law and technologically embedded values. In particular, the ability to embed contractual terms in technological artifacts now requires a re-examination of disclosure and consent in transactions involving such artifacts.

Key words: autonomy, biotechnology, clickwrap, code, content management, contract, copyright, genetic engineering, informed consent, plant variety protection, shrinkwrap, terminator, UPOV

Introduction

Human artifacts embody human values, but more than any other human artifact, information technology embodies within its design rules for its use. Biotechnology has now arrived as true information technology, permitting technological constraints to be purposefully programmed into genetic code. The emerging ability to program genetic code in this fashion blurs the line between law and artifact, and promises to challenge long-held assumptions in the legal regime of ownership and control over such biological artifacts.

This essay illuminates some of these emerging problems by drawing upon insights that have been developed in parallel discussions regarding digital technology, recognizing that those parallel discussions are themselves in their infancy, and may need to be enhanced or extended for my purposes here. In particular, this discussion highlights the problem of distinguishing coded constraints that we might treat as equivalent to law from other types of technologically embedded values. In doing so, the essay touches upon the broader questions involving long-standing discussions about contract laws effective application to technological constraints.

I shall begin by describing the recent advances in genetic design that allow constraints on the use of plants or other transgenic organisms to be programmed into the organism itself. I then show that this development parallels that in other programmable information technologies, and that current trends in the analysis electronic digital technologies may be properly applied to biological technologies. In particular, the development of programmable biological code ruises a series of difficult policy questions regarding the market power of commodity producers, the autonomous choices of commodity users, and the proper role of the state in regulating programmed constraints.

Coded constraints

Gene splicing techniques have enabled the creation of many types of sexually reproducing plants with commercially attractive characteristics: increased nutritional value, resistance to drought and pests, herbicide resistance, and medicinal properties, to name only a few.[1] The economic challenge to development of such plant varieties is that plants reproduce, as living organisms are wont to do. As a consequence, these new varieties are relatively expensive to create, but are trivially inexpensive to propagate once they are in existence – and, indeed, may propagate unintentionally. This 'public goods' problem of distribution at a marginal cost close to zero is common in other areas of innovation, even where the subject matter does not reproduce itself.[2] Legal prohibitions have been the typical solution to this problem, although technological solutions have also been employed. Both these strategies have now emerged in the case of genetically

[1] United States Congress Office of Technology Assessment. A New Technological Era for American Agriculture. U.S. Government Printing Office, Washington D.C., 1992.

[2] William M. Landes and Richard A. Posner. An Economic Analysis of Copyright Law. *Journal of Legal Studies*, 18: 325–363, 1989.

engineered plants, though with important and unusual characteristics not seen in previous incarnations of the problem.

Anti-germination technology

Society has primarily relied upon written rules to govern the use of biological inventions and in particular to address the public goods problem inherent in their creation. For example, in the United States, a form of intellectual property called Plant Variety Protection encourages development of new varieties of sexually reproducing plants by granting the developer broad control over the growth, use, importation, and sale of a new plant.[3] This American statute is a version of an international plant variety protection treaty, UPOV. As required under UPOV, the Plant Variety Protection Act includes some important exceptions to a seed developer's control, such as provisions allowing farmers to save seed from a proprietary crop, or permitting agricultural research involving the plant.[4]

Plant variety owners might prefer that their control over the variety were not subject to such exceptions, and so as a condition of access to their seeds, routinely require that farmers contractually waive their rights to save seed or engage in other legally permissible uses.[5] Often the terms of this contract are printed on or attached to the bag of seed; by using the seed, the contractual 'fine print' purports that the farmer has agreed to the terms. However, it is difficult to police the use of seed and to enforce the terms of such 'seed-wrap' licenses. To do so, seed developers must send agents out into farmers' fields to sample crops, looking for unlicensed users of proprietary seed. When such uses are found, costly legal procedures may be necessary to halt the use, force acceptance of a license, or recover unpaid royalties.

The problems of detection and enforcement might be lessened if seed could be designed to be 'self-policing,' that is, unsuitable for use without the developer's permission. Newly available transgenic technology allows for the creation of such 'self-policing' seed.[6] Genetic elements that produce a toxin late in seed development may be introduced into the plant variety.[7] The toxin kills the seeds after the plant has matured, producing a viable crop for the farmer, but forcing him to return to the seed producer for new seed each year. Even in the absence of a contractual obligation not to save seed, the technology makes saving seed impossible. Thus, the genetically altered seed in essence carries within its own makeup a prohibition on unlicensed use.

Indeed, the 'terms' of usage embedded in such genetic code may be quite sophisticated. In one embodiment of the technology, it is possible to introduce into the seed a genetic 'switch' that will repress, or turn off, the toxin production when the seed is exposed to a particular chemical. This in effect supplies a chemical 'password' to seed activate germination, and which can be used to control the terms of seed usage from year to year. Yearly application of the control chemical, obtained from the seed owner for payment, would allow the owner to activate or deactivate seeds in return for prescribed payment. One can easily envision other types of switches, sensitive to temperature, precipitation, soil alkalinity, or other environmental factors, that could be used to limit use of the seed to certain geographical regions or seasonal applications. Indeed, plants could be engineered for various desirable properties – pest resistance, drought resistance, superior yield, and so on – and particular attributes activated or deactivated depending on the price paid by the purchaser.

Although the patent on this technology is directed to control of plant development, similar genetic control elements are known in other organisms, and there is no particular reason that such technology need be confined to plants. Since the advent of genetically engineered animals, beginning with the 'Harvard Oncomouse,' the ability of the animal to reproduce has posed a challenge to the owners of proprietary rights in the organism: does the purchase of a patented animal confer the right to breed or use subsequent generations of the animal, and if not, how can the patent holder control subsequent generations?[8] Much as in the case of genetically altered seed, this problem has been largely handled via licenses that either include or exclude the right to breed the animal.[9] But once

[3] 7 U.S.C. § 2402.

[4] International Convention for the Protection of New Varieties of Plants, Dec. 2. 1961, as revised 33 U.S.T. 2703, 815 U.N.T.S. 89.

[5] Neil D. Hamilton. Legal Issues Shaping Society's Acceptance of Biotechnology and Genetically Modified Organisms. *Drake Journal of Agricultural Law*, 6: 81–117, 2001, pp. 90–91.

[6] Keith Aoki. Neocolonialism, Anti-Commons Property, and Biopiracy in the (Not-So-Brave) New World Order of International Intellectual Property Protection. *Indiana Journal of Global Legal Studies* 6: 11–58, 1998, p. 54.

[7] M.L. Crouch. *How the Terminator Terminates: An Explanation for the Non-scientist of a Remarkable Patent for Killing Second Generation Seeds of Crop Plants*, Edmonds Institute, 1998. (http://www.bio.indiana.edu/people/terminator.html)

[8] Rebecca Dresser. Ethical and Legal Issues in Patenting New Animal Life. *Jurimetrics Journal* 28: 399–435, 1988; United States Congress Office of Technology Assessment. *New Developments in Biotechnology: Patenting Life*. U.S. Government Printing Office, Washington D.C., 1989, p. 121.

[9] Robert P. Merges, Intellectual Property in Higher Life

again, due to policing and enforcement problems, as well as the opportunity for price discrimination, the availability of a genetic system to activate or deactivate a genetically engineered trait might be highly attractive to the creators of such animals.

The prospect of germ-line alteration of human subjects has been even more controversial although for somewhat different reasons, primarily relating to the ethical controversy of altering traits in future generations who have had no opportunity to consent to such alterations.[10] A full exploration of this issue is impossible within the scope of this essay, but I will note that some of the ethical objections to germ line therapy might be addressed by a control system that could deactivate germ-line therapies in future generations, unless perhaps they requested activation of the trait. A more likely, but no less troublesome application of the technology, might be found in somatic cell therapies. Genetic regulatory elements analogous to those in plant applications could equally well be added to the transgenic DNA cassettes contemplated for human gene therapy, placing recombinant genes in human cells under similar proprietary control.

One can easily envision genetic therapies for certain diseases, such as diabetes or hemophilia, which are caused by the failure of a particular gene in the body to produce a particular protein. A recombinant genetic 'cassette' containing a healthy copy of the defective gene could be introduced into the patient's cells in order to supply the missing protein.[11] The cassette could include regulatory elements allowing the gene to be activated or deactivated by administration of a proprietary pharmaceutical; so long as the patient were supplied with the pharmaceutical, the gene would continue to prevent the disease. Such a system might perhaps to allow the recipient to pay for the therapy over an extended period of time, rather than all at once. The supplier of the treatment could exercise self-help if payment were not forthcoming. Of course, under the current system, the supplier would presumably have legal recourse for non-payment, but for the reasons described above, self-help might be a more attractive form of recourse.

Content management technology

The description of seed licensing offered above bears an uncanny resemblance to the history of content licensing in digital media.[12] Digital technology offers inexpensive and widespread access to the means of reproducing and distributing copyrighted materials. As PVPA provides legal protection for seeds, copyright law affords the owners of digital content some recourse against many unauthorized uses of their material, but copyright is subject to a host of consumer uses that require no authorization from the copyright holder. Owners of digital content, much like seed owners, have long wished to escape the consumer privileges afforded by copyright law. They have done so through the fiction of the 'shrink-wrap' license, which purports to restrict a purchaser's use of the accompanying product.[13] The license takes its name from the legal fiction that the purchaser demonstrates agreement to the license terms by breaking the 'shrinkwrap' cellophane on the product package. More recently, such 'clickwrap' using the mouse to click on a graphic labeled 'I agree.'[14]

However, courts in the United States have in many cases been reluctant to enforce such agreements because the purchaser may have no opportunity to review the license prior to opening the package.[15] Proponents of mass-market licenses for software have complained that such agreements have long since been accepted in most other areas of commerce.[16] This observation is true, so far as it goes, but the consumer of, say, a car rental agreement has at least a nominal opportunity to read the agreement before the rental occurs; in the case of shrinkwrapped licenses, even the fiction of a pre-transaction opportunity to review is absent. 'Clickwrap' agreements similarly often involve after-market agreement to use software pre-installed

Forms: The Patent System and Controversial Technologies. *Maryland Law Review* 47: 1051–1075, 1988.

[10] LeRoy Walters and Julie Gage Palmer. *The Ethics of Human Gene Therapy*. Oxford University Press, New York, 1997.

[11] P.D. Robbins. Retroviral Vectors. In Thomas Blankenstein editor, *Gene Therapy, Principles and Applications*. Birkhauser, Basel, 1999, p. 18.

[12] Charles R. McManis, The Privatization (or 'Shrink-Wrapping') of American Copyright Law. *California Law Review*, 87: 173–190, 1999.

[13] David W. Maher. The Shrink-Wrap License: Old Problems in a New Wrapper. *Journal of the Copyright Society*, 34: 292–312, 1987; Deborah Kemp. Mass Marketed Software: The Legality of the Form License Agreement. *Louisiana Law Review*, 48: 87–128, 1987.

[14] Mark Lemley. Shrinkwraps in Cyberspace. *Jurimetrics Journal*, 35: 311–323, 1995.

[15] Mark Lemley. Beyond Preemption: The Law and Policy of Intellectual Property Licensing. *California Law Review*, 87: 111–172, 1999; Mark Lemley. Intellectual Property and Shrinkwrap Licenses. *Southern California Law Review*, 68(5): 1239–1294, 1995.

[16] Robert W. Gomulkiewicz and Mary L. Williamson. A Brief Defense of Mass Market Software License Agreements. *Rutgers Computer and Technology Law Journal*, 22: 335–367, 1996.

on a computer the consumer has already purchased. The situation has not changed appreciably with the advent of electronic commerce; proposed rules for information licensing would permit a merchant to change the terms of the agreement by posting the new terms somewhere on the Internet, or by sending the purchaser an e-mail message that would be considered effective even if the purchaser never actually received the message. In the face of uncertain enforcement by the courts, software vendors have sought to legitimate such practices by promulgation of the Uniform Computer Information Transaction Act, or UCITA, which has been adopted in two states.[17]

Yet even if such licenses become more frequently enforceable, it is still extremely difficult for copyright holders to police such agreements. Consequently, copyright owners have begun deploying sophisticated software 'lock-out' systems that prevent access to digitized content except on the terms dictated by the owner.[18] Such content management software may govern the number of uses, or their duration, or the payment schedule for additional access.[19] For example, access to technologically controlled content may be provisioned on agreement to a clickwrap-type license.[20] Similarly, the content management system may permit the owner to shut off the software remotely if the user fails to make the required payment in a timely manner; a controversial provision of the UCITA statute makes agreement to such 'self-help' a valid term of computer information licenses.[21]

In this environment where technology provides the first line of defense against unauthorized uses of content, the legal protection preferred by content owners may be not so much a deterrent against violation of copyright or similar proprietary rights, but legal deterrents against circumvention of technological protections.[22] In the United States, they have gained such protection in the form of the Digital Millennium Copyright Act, or DMCA, which prohibits circumvention of technical protection measures, and trafficking in technology that would facilitate such circumvention.[23] This statute effectively provides content owners a new right of technological access, independent of any intellectual property right. Language promulgating similar legal measures has appeared in a recent European Union copyright directive.[24]

The implications of this development are striking: By implementing technical constraints on access to and use of digital information, a copyright owner can effectively supersede the rules of intellectual property law. For example, as described above, the copyright owner may decide that the technological controls will not permit any copying of the controlled content, whether or not the copying would be fair use. If the integrity of the controls is backed by the state, as it is under the DMCA's anti-circumvention provisions, the result is to shift enforcement of the rights-holder's interest from penalties for unauthorized infringement to penalties for unauthorized access. When combined with UCITA provisions favoring the licensing terms promulgated by information producers, these developments dramatically alter the balance of ownership and control of new technologies.[25]

Toward lex genetica

It is important to underscore how this insight shapes the unusual nature of the genetic information issues that I have detailed above. There exists a large and rapidly growing literature addressing the legal and the ethical issues related to genetic information, and entire research programs devoted to expanding that literature. Contributions to that literature have typically focused on issues raised by genotechnology as a

[17] Niva Elkin Koren. A Public-Regarding Approach to Contracting Over Copyrights. In Rochelle Cooper Dreyfuss, Diane Leenheer Zimmerman, and Harry First, editors, *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society*, pp. 191–221. Oxford University Press, Oxford, 2001.

[18] Julie E. Cohen. Reverse Engineering and the Rise of Electronic Vigilantism: Intellectual Property Implications of 'Lock-Out' Programs. *Southern California Law Review*, 68(5): 1091–1202, 1995; Julie E. Cohen. Some Reflections on Copyright Management Systems and Laws Designed to Protect Them. *Berkeley Technology Law Journal*, 12(1): 161–187, 1997.

[19] Mark Stefik. Shifting the Possible: How Trusted Systems and Digital Property Rights Challenge Us to Rethink Digital Publishing. *Berkeley Technology Law Journal*, 12(1): 137–160, 1997.

[20] Michael J. Madison. Legal-Ware: Contract and Copyright in the Digital Age. *Fordham Law Review*, 67(3): 1025–1143, 1998.

[21] Eric Schlachter. The Intellectual Property Reniassance in Cyberspace: Why Copyright Law Could Be Unimportant on the Internet. *Berkeley Technology Law Journal*, 12(1): 15–52, 1997.

[22] Kenneth W. Dam. Self-Help in the Digital Jungle. *The Journal of Legal Studies*, 28: 393–412, 1999.

[23] Digital Millennium Copyright Act, Pub. L. No. 105–304, 112 Stat. 2860 (1998).

[24] Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonization of certain aspects of copyright and related rights in the information society, 2001 Q.J. (L. 167) 10.

[25] Niva Elkin Koren. A Public-Regarding Approach to Contracting Over Copyrights. In Rochelle Cooper Dreyfuss, Diane Leenheer Zimmerman, and Harry First, editors, *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society*, pp. 191–221. Oxford University Press, Oxford, 2001.

means of tampering with human genetics, either as a matter of medical treatment or of eugenics. But those issues, as important as they may be, are not our focus here. Rather, the question here relates to design of genetic products, the constraints or values embedded in those designs, and the ability of consumers to exercise choice regarding the use of those products.

Where technological constraints substitute for legal constraints, control over the design of information rights is shifted into the hands of private parties, who may or may not honor the public policies that animate public access doctrines such as fair use or a 'farmer's exemption.' Rights-holders can effectively write their own intellectual property statute in either software or DNA. This shift in control challenges the traditional role of the state in determining the limits of property and contract, as well as the accepted ethical assumptions underlying these legal institutions.

Lex informatica

The development of digital content management systems has been recognized as a graphic demonstration of the power of technology to regulate behavior. As both Larry Lessig and Joel Reidenberg have pointed out, technical standards are within the control of the designer, and so confer upon the designer the power to govern behavior with regard to that system.[26] Once constraints on behavior are built into the technical standards governing a technology, the technical standards effectively become a new method for governing use of that technology – in essence, the technical standards become a type of law. Such technical rule sets may supplement or even supplant the legal rule sets designed to govern the same behavior.

Consider, for example, an example suggested by Latour, in which the state wishes to enforce safety standards by requiring all automobile drivers to use seat belts.[27] One method to produce the desired behavior is to pass laws penalizing the failure to use such harnesses. However, an alternative method to produce the desired behavior is to fit automobiles with seatbelt interlocks that prevent the car's ignition from functioning unless the seatbelt is fastened to complete an electronic circuit. Thus, government may choose to employ or enforce technical standards to achieve goals that might otherwise be achieved by legal rulemaking. Such use of technological rules to govern behavior has been dubbed by Joel Reidenberg as 'lex informatica.'[28]

Reidenberg in particular has examined in detail the complex set of interactions through which governmental action can shape technological standards into a substitute for legal controls. For example, the state may implement the technological alternative through a variety of regulatory mechanisms, from a variety of sources. Most directly, the state might simply require automobile manufacturers to install seatbelt interlocks on all cars produced.[29] Alternatively, courts or legislatures acting through courts could impose liability for deaths or injuries on manufacturers who fail to install seatbelt interlocks, creating an incentive to include the feature in cars. Similar liability could be imposed on car drivers or owners, creating a consumer demand for manufacturers to install the devices.

Private lawmaking

The design of technological rule sets, however, is not the sole provenance of the state; indeed, it is more often left to private parties. In the case of digital content management systems, copyright owners determine the rules that are embedded into the technological controls. Moreover, to the extent that the DMCA appears to legitimate technological controls over copyrighted works, without regard to their effect on public policy, the statute effectively grants rubberstamp approval to such private legislation.[30] Although there exists, at present, no similar anti-circumvention statute for genotechnology, other private property statutes might be impressed into service to produce the same result. For example, the anti-germination technology described here is patented, so that attempts to tamper with it or reverse engineer it could constitute patent infringement.[31]

The development of such technological use controls, whether in either software or transgenic corn, has raised concern because it substitutes private technological rules for the public statutory rules declared by Congress in either the Copyright Act or the Plant Variety Protection Act. Producers who employ such lock-out technology may in essence become private legislatures, imposing rules of usage without regard to the broader public interest that informs democratic

[26] Joel Reidenberg. Lex Informatica: The Formulation of Information Policy Rules Through Technology. *Texas Law Review*, 76: 553–593, 1998; Lawrence Lessig. *Code and Other Laws of Cyberspace*, Basic Books, 1999.

[27] Bruno Latour. Where are the Missing Masses? The Sociology of a Few Mundane Artifacts. In Weibe E. Bijker and John Law, editors, *Shaping Technology/Building Society: Studies in Sociotechnical Change* pp. 225–258. The MIT Press, Cambridge, Massachusetts, 1992.

[28] Joel Reidenberg. Lex Informatica: The Formulation of Information Policy Rules Through Technology. *Texas Law Review*, 76: 553–593, 1998.

[29] Jerry L. Mashaw and David L. Harfst. *The Struggle for Auto Safety*. Harvard University Press, 1990.

[30] Niva Elkin-Koren. The Privitazation of Information Policy. *Ethics and Information Technology*, 2: 201–209, 2000.

[31] U.S. Patent No. 5,723,765 (Mar. 3 1998).

rule-making.[32] This problem has been well explored with regard to digital technology; the instantiation of a proprietary rule in genetic code, which following Reidenberg we might call 'lex genetica,' is the first example of the regulation by means of genetic code, but is unlikely to be the last.

Of course, the promulgation of technologically embedded rule sets is not the first situation in which private allocation of rights in information has been encouraged and enforced by public institutions. Most notably, the coercive power of the state is routinely brought to bear in the case of contractual agreements, such as confidentiality agreements and intellectual property licenses. Since technical controls can impose conditions that formerly might have been the subject of a detailed license agreement, such controls might be viewed as equivalent to a sort of licensing regime. Then, extending the analogy, penalties for circumvention of the technological constraints simply stand in for the private law of contract, which penalizes breach of license.

But such a comparison to contract law by no means justifies employment of technical controls that contravene established public policy. Where traditional contracts are at issue, carte blanche enforcement of private agreements has never been the rule in Anglo-American law. When such agreements are found illegal, unconscionable, or simply in violation of public policy, they are deemed unenforceable.[33] Because contract law is state law, a similar result also may be reached on grounds of federalism: where enforcement of a state law contract would violate the public policy inherent in the federal intellectual property scheme or embedded in the United States Constitution itself, such contractual provisions are preempted. An attempt to leverage the federal statutory right beyond the limits set by federal policy constitutes grounds for voiding the contract.

To the extent that 'code' confronts us with behavioral constraints that are somehow analogous to legally-enforceable contractual provisions, we presumably face much the same dilemma with regard to hardwired constraints that we have previously faced when dealing with contractual constraints. This point has perhaps been argued most forcefully by Julie Cohen, although not in precisely these terms, when she opines on the potential for constitutional preemption of certain technological content management constraints.[34] Cohen suggests that the coercive power of the state should be extended in support of technological constraints no farther than it may be extended to enforce statutory or contractual constraints. This conjecture, which Lessig has dubbed the 'Cohen Theorem,' might be applied in either private or public law settings to restrain the implementation of technological constraints by either individuals or the state.

Under the 'Cohen Theorem' analysis, there is no reason to suppose that technological analogs to contracts should be privileged over the legal instruments themselves. Where rights management systems attempt to impose restrictions on access to or use of informational content that would be improper in a contractual agreement, the restrictions should be viewed as equally repugnant to public policy and equally void. Stated differently, where the Constitution imposes limits on the government's creation and recognition of property rights in intellectual goods, those limits apply equally to both legally and technologically delineated property. In some instances of overreaching via technological controls, the Constitution may even demand a limited self-help right, or 'right to hack,' to surmount privately erected technological barriers to information that the Constitution requires be publicly accessible.

It is less clear what might form the jurisprudential basis for such a right outside the context of digital technology. The tension between free speech and copyright is well-defined and well-documented, and the limits upon Congressional power have been the subject of long scrutiny; technological controls over creative works are only the most recent chapter in that policy discussion. Biological controls lack any similar policy precedent. Unlike content management systems, anti-germination systems do not implicate a fundamental human right to receive information. No court has ever recognized a constitutional right to save seed, or to engage in agricultural research. Some commentators have argued in favor of a general First Amendment right to engage in scientific research,[35] but the legitimacy of such arguments is unsettled, and their application to proprietary organisms uncertain.[36]

[32] J.H. Reichman and Jonathan Franklin. Privately Legislated Intellectual Property Rights: Reconciling Freedom of Contract With Public Good Uses of Information. *University of Pennsylvania Law Review*, 147(4): 875–970, 1999.

[33] Restatement (Second) of Contracts, § 178.

[34] Julie E. Cohen. Copyright and the Jurisprudence of Self-Help. *Berkeley Technology Law Journal*, 13(3): 1090–1143, 1998.

[35] Harold P. Green, Constitutional Implications of Federal Restrictions on Scientific Research and Communication. *UMKC Law Review*, 60: 619–643 (1992); Richard Delgado & David R. Millen. God, Galileo, and Government: Toward Constitutional Protection for Scientific Inquiry. *Washington Law Review*, 53: 349–404, 1978; John A. Robertson, The Scientist's Right to Research: A Constitutional Analysis. *California Law Review*, 51: 1203–1281, 1977.

[36] Roy G. Spece, Jr. & Jennifer Weinziel, First Amendment Protection of Experimentation: A Critical Review and Tentative

Where lex genetica is applied to the human body, the established jurisprudence of rights may prove somewhat more fruitful. Certain Supreme Court holdings suggest a constitutional right to bodily integrity,[37] as for example where state-sponsored invasive procedures would 'shock the conscience.'[38] Other cases establish a constitutional prohibition against intrusive state intervention into personal or medical decision-making, especially in reproductive matters, although the exact parameters of this right tend to shift from year to year.[39] Such constitutional guarantees might override contractual or patent prohibitions against tampering with biological controls, but it is difficult to know what type of genetic programming might be considered sufficiently 'shocking' or intrusive to invoke such rights. Moreover, even if a sound legal basis for overriding legal protections can be found, the practical implementation of a 'right to hack' may be problematic outside the context of digital technology. There appears to be no comparable community of biological 'hackers' who might either personally have the skill to circumvent biological lock-out coding, or to supply users with the tools to circumvent such code.

Technological scripts

Technical controls on digital or biological systems therefore challenge the existing order of control and ownership for technology. However, the concept of technological constraints predates programmable artifacts. The idea that technology embodies rules is not new. Bruno Latour identified the 'scripted' nature of different artifacts, pointing out for example that automobile seatbelts with ignition interlocks embody a type of 'script' requiring a driver to take the particular action of fastening the seatbelt before driving.[40] Similarly, a locked door effectively embodies a rule against unauthorized entry. These artifacts are not programmable in the sense that software or DNA may be programmed with a wide range of attributes, but nonetheless the physical construction of the door enforces its particular prohibition, just as the electro-mechanical 'script' of the ignition interlock enforces its particular prohibition.

Thus, although programmability certainly increases the range and complexity of artifactual 'scripts,' this may represent a difference of degree, rather than a difference of kind. Myriad user constraints are built routinely built into all kinds of artifacts, and all of them will entail some set of values: the hinge design causes the door to swing in a particular direction, the doorknob is set at a particular height and requires a certain degree of manipulation to open, and so on. Many of these constraints go unnoticed as part of the artifactual backdrop of society, while other constraints implicate important social values, either supporting or frustrating such values. Such effects may be intentional or unintentional; the door may be unintentionally difficult for physically disabled persons to open, or may be intentionally difficult for small children to open, or may even unintentionally frustrate use by the physically disabled precisely because it was designed to retard use by small children.

The creation of such artifactual 'scripts' may be influenced by state action. As suggested by the seatbelt example above, technological design may be either directly or indirectly determined by a range of regulatory interventions.[41] But in market based economies, such intervention is typically limited to design features that have a noticeable effect on public health or safety, or to extraordinary regulation, such as removal of architectural barriers to the disabled. The vast majority of technological choices go largely unregulated, as we primarily entrust to market forces the task of weeding out over time the most inefficient or unusable designs. Although it is understood that such markets may be subject to network effects, incomplete information, and a wide range of market failures that could in fact hamper the efficient development of such designs, the market approach is assumed on the whole to operate more ably than command and control intervention by the state. At the same time, this market approach itself undoubtedly imbues the resulting artifacts with particular embedded values.

At the same time, users of any given technology will for the most part be unaware of the values embedded in a given technological system. Indeed, this is one of Reidenberg's key objections to a wholly 'free market' approach to information tech-

Synthesis/Reconstruction of the Literature. *Southern California Interdisciplinary Law Review*, 8: 185–228, 1998; Gary L. Francione, Experimentation and the Marketplace Theory of the First Amendment, *University of Pennsylvania Law Review*, 136: 417–512, 1987.

[37] Cruzan v. Director, Missouri Department of Health, 497 U.S. 261 (1990); Stenberg v. Carhart, 120 S.Ct. 2597 (2000).

[38] Rochin v. California, 342 U.S. 165 (1952).

[39] Skinner v. Oklahoma, 319 U.S. 535 (1942); Griswold v. Connecticut, 381 U.S. 479 (1965); Eisenstadt v. Baird, 405 U.S 438 (1972); Roe v. Wade, 410 U.S. 113 (1973); Washington v. Glucksberg, 521 U.S. 707 (1997).

[40] Bruno Latour. Where are the Missing Masses? The Sociology of a Few Mundane Artifacts. In Weibe E. Bijker and John Law, editors, *Shaping Technology/Building Society: Studies in Sociotechnical Change*, pp. 225–258. The MIT Press, Cambridge, Massachusetts, 1992.

[41] Jerry L. Mashaw and David L. Harfst. *The Struggle for Auto Safety*. Harvard University Press, 1990.

nology development: that all unknown to the general populace, it cedes to technologists choices that may later dictate the freedom or constraints upon users.[42] Reidenberg's preferred solution appears to be one of governmental oversight or involvement, at least in democratic states. Governmental bodies may exercise such oversight through a variety of channels, including direct regulation, standard-setting, procurement, criminal or civil penalties, and so on. Reidenberg reasons that involvement by elected officials, or at least by bureaucrats answering to elected officials, presumably better reflects democratic values than leaving the choice to technologists.

But as detailed above, explicit legal or regulatory intervention into technological design is relatively rare. Unless we are willing to countenance wholesale state oversight of every routine design decision, we must somehow separate out those design constraints that implicate public policy from those that we have previously treated as innocuous, or at least as routine. This separation has long been taken for granted; in a conventional transaction involving the use or exchange of an artifact, we have typically separated the values embedded in the artifact from the disembodied values instantiated in the law governing the transaction. For example, when a consumer purchases an automobile featuring seat belt interlocks, we could conceptualize as a term of the transaction, embedded in the artifact, 'the purchaser will be required to fasten her seatbelt prior to driving.' We have not done so, however, and in fact tend to separate even a public legal requirement to use seatbelts from the terms of the private transaction; no promise to use seatbelts is written into automobile sales contract or leases, despite laws requiring seatbelt use.

To be sure, some regulatory intervention may occur at the point of legal transaction if the nexus between the two seems sufficiently close. The licensing of the vehicle, or transfer of the license, may be incorporated into the transaction, if for no other reason than it provides a convenient control point for the state to ensure that such licensing occurs. But conceptual nexus for such incorporation has been relatively rare. Returning to the case of the automobile, other regulatory interventions, such as the requirement that the driver be licensed, or carry proper accident insurance, appear to have an insufficient nexus with the sale of the vehicle.

In much the same way, explicit legal or regulatory intervention into 'private lawmaking' via contract is relatively rare. If our past experience with law in fact maps onto the territory of technological constraints, we would expect only a subset of such constraints to trigger legal safeguards, such as the Cohen Theorem – the vast majority of both private and public lawmaking goes relatively unremarked, routinely functioning without the application of extraordinary judicial or constitutional remedies. Only a small number of contracts are struck down as unconscionable or void for public policy, just as few statutes are struck down as unconstitutional. Yet the current literature analyzing technological constraints gives no clear guidance on where routine or garden variety design choices may begin to shade over into legally cognizable constraints, or which legally cognizable constraints should be the abrogated as contrary to existing public policy.

Taking code seriously

Summing up to this point: I have argued that the advent of programmable technical constraints creates two intertwined difficulties: first, determining where legally cognizable technology choices leave off and routine, if sometimes troubling technology choices begin; and second, once legally relevant technology choices have been identified, determining how social policy choices that have been implemented in law will be implemented in its technological analogs. Moreover, the lines drawn in each case may differ according to the technology involved, as biological 'lock-out' systems arise in a different milieu than analogous digital control mechanisms. To illustrate these issues, I turn now to the specific example of translating to programmed artifacts the values of autonomy as they have been instantiated in the substantive law of contract, as well as in relevant principles of informed consent.

Law and autonomy

Modern contractual theory incorporates concepts of autonomy under two broad categories. The first of these categories focuses directly on the importance of contract as a means of promoting individual choice or autonomy, or on autonomy as an animating principle to justify a theory of contract.[43] The second broad category of contractual theory focuses on efficiency as the primary purpose of contract. These latter 'law and economics' formulations of contract owe much to the utilitarian tradition, but focus on maximization of wealth as a proxy or substitute for ensuring the greatest

[42] Joel Reidenberg. Lex Informatica: The Formulation of Information Policy Rules Through Technology. *Texas Law Review*, 76: 553–593, 1998.

[43] Randy E. Barnett. A Consent Theory of Contract. *Columbia Law Review*, 86: 269–321, 1986.

happiness to the greatest number of people.[44] Under such theories, individual choice still plays a central role in implementing the decentralized allocation of resources; by encouraging self-interested activity with minimal outside interference, resources are moved to their optimal use. Thus, in this second set of theories, autonomy functions within this framework as a means to an end, rather than as an end in itself. At the same time, some apologists for an economic approach have melded the two theories, turning the relationship between autonomy and efficiency around to argue that a market-based approach to contract is desirable because it promotes autonomy.[45]

Under either set of theories, excessive governmental intervention into the bargain may be decried as 'paternalism' or interference with the autonomy of the parties. But the focus on autonomy in private bargaining creates a potential paradox regarding state intervention, or paternalism. State intervention into the transaction may be decried as an imposition on the autonomy or contractual freedom of the parties. At the same time, state intervention may be necessary to preserve the autonomy or contractual freedom of certain parties, particularly where one party stands in a position of overwhelming power or influence. Typically such asymmetrical bargaining positions are perceived to occur where one party has far more information than the other, or where one party's range of choices are highly constrained due to lack of competitive alternatives. In such situations, the terms of the agreement may be perceived as imposed by the stronger party, without the free consent of the other. The classic case for such asymmetrical bargains are mass-market consumer transactions, where a large corporate entity may have access to far more information about a product than the typical consumer, or where the consumer's bargaining choices may be limited to few or even one vendor. Either situation may be conceived in an economic framework as a form of market failure; were the market to operate perfectly, market forces would act to discipline contractual overreaching.

Such market failure situations may in fact be very common, but where the social system puts its faith in markets, the law assumes that they will be rare. The tradition in Anglo-American law has been that for the most part, the state avoids intervention into particular terms of the contract. Courts typically refuse to inquire, for example, into the adequacy of consideration.[46] The state may withhold its coercive power in those rare cases where a party falls into a category clearly classified as lacking legally cognizable autonomy, such as that of minors or the mentally incompetent.[47] Equally rarely, a court may invoke a doctrine such as unconscionability to protect otherwise competent parties, and most especially individual consumers, from exploitation by more powerful or better informed parties.[48] Autonomy may also be husbanded in unusual situations by other doctrines, such as recission,[49] misrepresentation,[50] or mistake,[51] that might be viewed as designed to nullify agreements a party has entered into without full information, which may be to say without full autonomy.

However, such doctrines are invoked rarely and with some reluctance because of their potential to supersede 'freedom of contract.' Judges are reluctant to override terms that may have been the preference of the contracting parties. Libertarian analysts denounce the doctrines for introducing the heavy hand of the state into private bargaining. Economic analysts decry the potential for inefficiency. Even analysts outside the free-market economics tradition may be wary of such doctrines because they are highly interventionist – assuming, for example that certain classes of individuals cannot understand contractual terms or cannot formulate a legally recognizable desire to be bound by contractual terms. The historical inclusion of women together with children and mentally handicapped individuals as legal incompetents amply illustrates the objection that imposition of judicial preferences may be dangerous to individual autonomy.

Consequently, although the state may forbid or invalidate certain contractual terms, it will more often intervene by mandating disclosure of terms. For example, certain key terms to a mass-market contract must be 'conspicuous,' which typically means printed in a larger, bolder, or more prominent typeface than terms considered less important or less potentially troublesome.[52] Similarly, under conditions requiring medical consent, physicians may be required to be especially forthcoming regarding particularly trouble-

[44] Jeffrie Murphy and Jules Coleman. *Philosophy of Law: An Introduction to Jurisprudence*, 2nd ed. Westview Press, 1990.

[45] Richard Posner. The Ethical and Political Basis of the Efficiency Norm in Common Law Adjudication. *Hofstra Law Review*, 8: 487–507, 1980; Richard Posner. Utilitarianism, Economics, and Legal Theory. *Journal of Legal Studies*, 8: 103–140, 1979.

[46] Restatement (Second) of Contracts, § 79; E. Allen Farnsworth. Farnsworth on Contracts § 2.11, 2000.

[47] Restatement (Second) of Contracts, § 12.

[48] E. Allen Farnsworth. *Farnsworth on Contracts*. § 4.28, 2000.

[49] Restatement (Second) of Contracts § 283.

[50] Restatement (Second) of Contracts § 164.

[51] Restatement (Second) of Contracts § 153.

[52] Uniform Commercial Code § 2-316(2); E. Allen Farnsworth. *Farnsworth on Contracts*. § 4.29a, 2000.

some risks or outcomes attending a treatment. Such 'paternalism light' is intended to secure autonomous decision making by ensuring that information deemed important to a decision is available, without dictating the decision itself. This approach is, of course, laden with important underlying assumptions that the recipient of the information both understands the information provided and has the circumstantial latitude to act freely on it, and the more interventionist doctrines may be invoked in those unusual occasions where the law may believe such latitude is lacking.

In the case involving human application of genetic programming, a second source of autonomous consent comes into play, that of informed medical consent. In the context of medical treatment, the question of autonomy had played a somewhat different role, as the focus is on assent and authorization, rather than upon contractual consideration. The issue here is typically not framed as one of contract, perhaps because the problem is seldom conceived in terms of a bargained-for exchange. Patients whose medical treatment proves sub-standard are seldom interested in a contractual remedy, such as getting their money back; neither are human research participants who are subjected to unconsented research procedures, interested in demanding performance of the experiments to which they thought they had agreed. Under the Anglo-American legal system, such a claim sounds in tort rather than contract, in large part due to the development of informed consent out of the waiver doctrine in law of battery.[53]

Consequently, in matters of informed consent, the stigma of paternalism is not directed to the imposition of governmental restraints on the parties bargaining, but to the imposition of the physician's preferences or decisionmaking upon the patient. The autonomy question is less an issue of governmental intervention than one of medical intervention: the assumption of a decisionmaking role by the physician.[54] The issue of governmental intervention is of course lurking in the background. Legal duties may be imposed on a physician, perhaps mandating a certain level of disclosure, discouraging or prohibiting certain interventions without proper consent, or in rare cases, requiring intervention regardless of consent. Yet governmental paternalism has received relatively little attention in this context, perhaps because it is assumed that one party to the transaction – the physician – is routinely and uniformly in possession of asymmetrically greater information and situational control. Thus, unlike the contract situation in which arm's length bargaining is routinely assumed, in the informed consent setting, market failure is routinely assumed.

Code and autonomy

Bargained-for contract and informed consent may thus be viewed as polar opposites in the approach to disclosure and the preservation of a legal regime of autonomy. Their commonality lies in the underlying assumption that first line of defense in preserving autonomy, or at least the semblance of autonomy, should be the requirement of disclosure; for both market contracting or medical consent, autonomous consent given in either setting requires information upon which to decide. But in past situations, even where both sets of obligations might be present, they could be treated under entirely different assumptions: one for the bargained-for transaction, and one for treatment, each requiring a different duty of disclosure. While the process, effects, and outcomes related to the treatment might in some sense have been considered terms of the business transaction, the persistent asymmetry of information and control, favoring the physician, gave rise to disclosure requirements never seen under the rubric of contract.

But this compartmentalization of assumptions begins to blur when the features of the technology coincide with the terms of the transaction. Programmable biological elements, when used for human treatment, make the terms of the bargain a characteristic of the treatment. And even where human treatment is not involved, the same persistent asymmetry of information will exist. Courts have shown some reluctance to enforce written shrinkwrap licenses where information material to the transaction is disclosed subsequent to the transaction. Adherence to 'freedom of contract' in such situations may be little more than a sham, and the resistance to state intervention little more than an excuse to give the more powerful party in the transaction the maximum latitude to impose unrestrained oppressive or overreaching terms. The potential for abuse is far greater when the information material to the transaction is never disclosed, but remains embedded in the artifact – the consumer and producer of the artifact stand in a relationship of persistent informational asymmetry, much like the relation of the physician and patient under informed consent.

This suggests a pressing need to equalize the informational disparity, but if disclosure is to be the mechanism for equalization, the precise contours of the needed disclosure remain problematic. In the contractual setting, disclosure requirements have

[53] Ruth Faden and Thomas Beauchamp. *A History and Theory of Informed Consent*. Oxford University Press, New York, 1986.

[54] Carl Schneider. *The Practice of Autonomy*. Oxford University Press, New York, 1998.

typically been limited to terms considered 'material' to the transaction – terms such as warranties, disclaimers, and remedies. Design choices or embedded technological values have simply not been part of that constellation of terms. The rare instances where design choices are the subject of disclosure tend to arise in the area of products liability, where an industrial product is found to have dangerous characteristics not apparent upon consumer examination.[55] Much as in the case of informed medical consent, disclosure of the potential danger allows the manufacturer of the product to avoid liability for injury by virtue of the consumer's voluntary acceptance of the danger. But non-dangerous design choices are typically mandated by neither contract nor tort theories. Courts do not require that an automobile seller reveal, for example, that a car was designed on the assumption that exhaust manifolds would need replacement every 10 years, or that gasoline prices would remain at $1.35 per gallon, or that automobile factory worker's wages would remain stable, or that state law on 'plug-molds' would continue to provide a cheap source of replacement automobile body parts, or that Americans in the next decade would value mobility over ecology.

Indeed, the law has been somewhat hostile to mandating disclosure when technologies render products that are not materially different, but morally different. In those rare instances where consumers have displayed an interest in knowing, for example, where particular meats originated, or whether recombinant gene products were used in the production of milk or vegetable produce, both courts and legislatures have been resistant to imposing a legal disclosure requirement.[56] In some of these cases, market demand has prompted producers to provide products carrying the desired disclosures, obviating the need for legal or political intervention.[57] But where a market for the information has not developed, there has to date been little state intervention to solve the market failure, or to force disclosure for the sake of a broader conception of informed product consent.

Thus, if disclosure is to remain the first line of defense in protecting contractual autonomy, re-evaluation of our previous approach to disclosure seems in order. Although the purchaser of seed may have the opportunity to read the agreement on the side of the bag, he has no ability to examine the programming of a seed, and cannot determine its constraints by examining the product, anymore than the patient has the ability to divine the likely outcome of a medical procedure. Human applications of 'lex genetica' offer the clearest case for an increased duty of disclosure, but the same considerations will remain in other applications. Preservation of the value of autonomy in the face of embedded terms requires the creation of criteria to determine when an embedded term is legally relevant, and then determination of the level of state intervention that is appropriate. At a minimum, this likely means mandating disclosure of biological product characteristics that are material to the use of the product.

[55] Restatement (Third) of Torts: Products Liability § 2(c).

[56] Dan L. Burk. The Milk-Free Zone: Federal and Local Interests in Regulating Recombinant BST. *Columbia Environmental Law Review*, 22(2): 227–317, 1997.

[57] This has occurred, for example in the case of milk from cows treated with recombinant bovine somatotropin (rBST), to which some consumers may have social or moral objections, in response to which the producers have supplied milk from untreated herds at a higher price.

Conclusion

This essay closes having likely raised more questions than it has answered. That was in part the intent; to indicate how sparse is our current understanding of technological constraints as a matter of policy, and in particular the need for some criterion to distinguish relatively routine technological constraints that might deserve a social response from extraordinary constraints that deserve a legal response. But at the same time, this discussion moves us closer to answering such questions by demonstrating how current analysis of technological constraints may be extended. The development of biologically programmable artifacts indicates that the issue is a general question of technology policy, and not idiosyncratic to digital technology such as the Internet.

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